## REMARKS

In the present Office Action, claims 1-4, 6-13 and 15-38 were examined. No Claims are subject to restriction or election. Claims 1-4, 6-13 and 15-38 are rejected, no claims are objected to, and no claims are allowed.

By this Amendment, claim 19 has been amended, claim 6 has been canceled, and no claims have been added. Accordingly, claims 1-4, 7-13 and 15-38 are presented for further examination. No new matter has been added. By this Amendment, claims 1-4, 7-13 and 15-38 are believed to be in condition for allowance.

The Examiner is also respectfully requested to note the previously made amendments to claims 20, 21, 22, 24-29, 31 and 35 in the previously submitted Preliminary Amendment that accompanied the RCE Transmittal. It appears the Examiner did not fully appreciate those Amendments with respect to the present Office Action.

Explanation of Above Amendments

The amendment to page 11 of the specification is merely to explicitly define what a "data carrier" is in the present application. No new matter is intended or believed to be included by this amendment.

The amendments to claim 19 are to make clear that the data carrier is separate from the claimed drug delivery system for this embodiment of the presented invention.

Rejections/Objections under 35 USC §112

The Examiner rejected claims 1-4 and 6-12 under 35 U.S.C. §112, second paragraph. Applicant respectfully traverses this rejection by the above cancellation of claim 6.

Rejections under 35 USC §102

The Examiner rejected claims 1-4, 6, 7 and 9 under 35 U.S.C. §102(b) as being anticipated by Castellano et al. (U.S. Patent No. 5,593,390). In making this rejection the Examiner stated the following:

> "Castellano et al. teaches a drug package comprising: a plurality of drug vials; an electronic data carrier separate from the drug vials, the carrier including drug treatment information (col. 9, lines 15-26); wherein the data carrier is arranged to include at least one of the following items of treatment information: the dose of drug to be delivered; the identity of the drug which is to be delivered; the expiry date of the drug to be delivered; and the number of treatments available from the drug package (col. 6, lines 6-22); wherein the drug vials contain drugs adapted for delivery in air inhaled by a patient to their lungs; wherein the drugs vials are arranged to be used in conjunction with a drug delivery device (col. 2, lines 52-56), wherein the data carrier is arranged to transfer treatment information to a drug delivery device when it is moved to a receptive surface or region of the drug delivery apparatus 446; wherein the data carrier is arranged to supply drug treatment information to a drug delivery device a number of times corresponding to the number of treatments available from the drug package, or the number of vials included in the drug packages (col. 2, lines 59-67); wherein the data carrier is a radio frequency device; and wherein the data carrier includes a memory for recording information concerning treatments received from the drug delivery device."

Applicants respectfully traverse this rejection for the following reasons.

With respect to all of these claims, Castellano does not disclose a plurality of drug vials in its pen-type medication delivery device. Furthermore, its pen-type medical device is not being suppliable to the patient in a drug package.

The Examiner also rejected claims 13, 15, 16, 18, 20 and 21 under 35 U.S.C. §102(b) as being anticipated by Castellano et al. In making this rejection, the Examiner stated the following:

> "Castellano teaches a drug delivery apparatus comprising: a delivery portion 28; an electronic input (col. 9, lines 15-26); a delivery controller; wherein the input is a radio frequency input which receives the treatment information from a data carrier at radio frequency (col. 9, lines 15-26);

> wherein the input is additionally arranged to transmit completed treatment information to the data carrier (col. 9, lines 15-26); wherein the drug delivery apparatus is one of a pneumatic nebulizer, a piezo-electric nebulizer and an ultrasonic nebulizer (col. 23, lines 9-12); and a medication chamber 16."

Applicants respectfully traverse this rejection for the following reasons:

Castellano does not appear to disclose an electronic data carrier which can be physically removed (i.e. "remotely") from the drug delivery device in order to transfer data. Therefore, claim 13 is novel.

With respect to claims 20 and 21 the electronic data carrier in each of these two claims is also claimed as being separate from the drug delivery device. This is also a clear distinction from Castellano.

Furthermore, the Examiner rejected claim 19 under 35 U.S.C. §102(b) as anticipated by Wolf et al. (U.S. Patent No. 5,505,195). In making this rejection, the Examiner stated the following:

> "Wolf et al. teaches an electronic data carrier for use with a drug delivery apparatus comprising a memory located within the data carrier for holding treatment information concerning the use of a drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 11, lines 41-58).

This rejection also respectfully traversed for the following reasons:

The Examiner again appears to have failed to appreciate that the electronic data carrier as now claimed is separate from the drug delivery device, and that the data carrier is detachable from the delivery device, and that it is supplied separately from the drug delivery device.

Claim 19 has been further amended to assist the Examiner in understanding how the present invention is distinguished over the prior art.

Rejections under 35 USC §103

The Examiner rejected claim 17 as being obvious under 35 U.S.C. §103(a) over Castellano et al. taken in view of Wolf et al. In making this rejection, the Examiner stated the following:

> "Castellano et al. teaches the drug delivery apparatus according to claim 13. It should be noted that Castellano et al. fails to teach wherein the drug delivery apparatus includes an authorization portion which prevent delivery if any of the treatment information indicates that the drug is unsuitable for delivery. However, Wolf et al. teaches wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery. Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Castellano et al. to include the authorization portion of Wolf et al. to insure proper activation (col. 11, lines 24-34)."

Applicant respectfully traverses this rejection for the same reasons as claim 13 is distinguished over the primary reference.

The Examiner also rejected claims 22 to 38 under 35 U.S.C. §103(a) as being unpatentable and obvious over Wolf et al., taken in view of Eigler et al. (U.S. Patent No. 6,328,699). In making this rejection, the Examiner stated the following:

> "As to claim 22, Wolf et al. teaches a drug deliver device comprising: a delivery portion for delivering a drug to a patient 140; a drug use analyzer which records the use of the drug over a number of treatments and which identifies when only a certain proportion of the prescribed drug remains (col. 13, line 52-67). It should noted that Wolf et al. fails to teach a repeat prescription ordering portion which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient. However, Eigler et al. does teach a repeat prescription ordering portion (col. 10, lines 60-65) which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment

information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient (col. 10, lines 8-45). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. to include the repeat prescription ordering portion of Eigler et al. to ensure that the user has a new supply of the drug before the drug in the device is exhausted and to insure the proper amount of drug is being used.

Wolf/Eigler teaches wherein the repeat prescribed ordering portion includes a modem which automatically connects to a telephone system to electronically order a repeat prescription (col. 13-26); wherein the repeat prescription ordering portion includes a connection to an electronic network through which the repeat prescription is ordered (col. 10, lines 60-65); wherein the drug use analyzer includes a counter for counting the number of drug treatments delivered (col. 13, lines 52-67); wherein the drug analyzer includes a memory for holding the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, lines 52-67); wherein the drug use analyzer includes a comparator which compared the number of drug treatments that are possible from the memory with the number of drug treatments delivered from the counter, and generates a repeat prescription order signal when only a certain proportion of the prescribed drug remains (col. 13, lines 52-67); wherein the repeat prescription re-ordering portion orders a repeat prescription once it received a repeat prescription order signal from the drug use analyzer (col. 10, lines 60-65); wherein the drug use analyzer includes a data carrier, including drug treatment information including the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, line 52-67); wherein the memory for holding the total number of drug treatments is located in the data carrier (col. 13, lines 52-55).

As to claim 31, Wolf/Eigler teaches a method of prescribing a drug, comprising: supplying a patient with a course of a number of drug treatments 623 for administering using a drug delivery device; recorded treatment information to a data center once only the certain proportion of the drug treatments are identified as remaining (col. 10, lines 60-65); analyzing the recorded treatment information of the data center according to a protocol in order to formulate a result which identifies whether certain specifications are satisfied, and where the result indicates that certain specification have not been satisfied, referring the patient to a doctor (col. 10, lines 8-45); issuing a course of drug treatments or a prescription for the course of treatments in response to the electronic order (col. 10, lines 60-65); wherein the electronic ordering is done via a connection to an electronic network (col. 10, lines 60-65); wherein the analyzing of the use of the drug treatments includes counting the number of drug treatments

delivered (col. 13, lines 52-67); wherein the analyzing includes the comparing of the number of drug treatments delivered with the total number of treatments supplied (col. 13, lines 52-67); further including the step of generating a repeat prescription order signal when it is identified that only a certain proportion of the drug treatments remain (col. 10, lines 60-65); and further comprising the supply of a data carrier with the course of a number of drug treatments, the data carrier bearing drug treatment information including the total number of drug treatments that are possible from the existing course of drug treatments (col. 13, lines 52-67).

Applicant also respectfully traverses this rejection for the following reasons:

Presented claims 22 to 38 are directed to either a system or process whereby, on the basis of analysis in the claimed data center, either the patient is referred to a doctor for treatment, or if the specifications are met, a repeat prescription is generated.

The point that a repeat prescription is automatically generated when the measured specifications are met is a critical feature of this embodiment of the present invention. Basis for this can be found on page 15, lines 468 to 472.

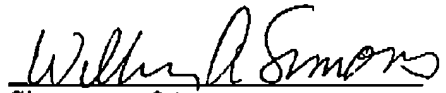
In contrast, neither Wolf et al., or Eigler et al. discloses such a direct dispensing of a prescription or drug. In the Wolf et al. patent, the doctor conducts the analysis, and in Eigler et al. the initial information is provided first to the patient to change his therapy in response to signals. The patient must then get a new prescription. Eigler et al. also suggests in column 10, lines 60 to 65 that any analysis will be conducted when the information is sent back to the hospital doctor or pharmacy. Neither of the prior art documents discloses what is disclosed in the flow chart of Figure 5 where the data analysis and protocol is conducted at a data center prior to requesting more medication from a pharmacy or contacting a doctor. Thus, the present invention provides an effective automatic service to these customers where a doctor or a pharmacy does not have to analyze the data directly.

Accordingly, Applicant submits that none of the references, alone or in combination, anticipate or make obvious the invention as presently claimed and that the application is now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and further examination of the application and the Examiner is respectfully requested to take such proper actions so that a patent will issue herefrom as soon as possible.

If the Examiner has any questions or believes that a discussion with Applicant's attorney would expedite prosecution, the Examiner is invited and encouraged to contact the undersigned at the telephone number below.

Please apply any credits or charge any deficiencies to our Deposit Account No. 23-1665.

Respectfully submitted,
Jonathan Denyer, et al.



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